

K964523

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510(K) SUMMARY
(as required by 807.92(c))**Submitter of 510(k):**

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Date of Summary:

October 18, 1996

Trade Name:

Recover® Infant Heel Warmer

Classification Name:

Pack, Hot, Disposable

Predicate Device:

Florida Medical Industries, Recover® Infant Heel
Warmer Pre 1976 Device

**Device Description/
Comparison:**

Non Toxic, Food Grade Sodium Acetate and water
with a stainless steel catalytic disc sealed in a nylon
/polyethylene laminate bag. Provides heat to 105°F.

	Proposed Device	Marketed Device
	Florida Medical Industries	Florida Medical Industries
Contents	Food-grade sodium acetate and water. Disc: Stainless Steel Catalytic disc.	Magnesium Sulphate (Kieserite); Colloidal Clay; water.
Temp.	105°	105°

Intended Use:

The Recover® Infant Heel Warmer is intended to be used for warming the heel site of an infant prior to a heel stick procedure. The warmth enhances vasodilation and increases blood flow in an infant's heel to ensure adequate blood for sampling.